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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/747,155 | 12/21/2000 | Sylvie Rouquier | 19904-008 | 9730 |

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EXAMINER

BRANNOCK, MICHAEL T

ART UNIT PAPER NUMBER

1646

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/747,155

Applicant(s)

ROUQUIER ET AL.

Examiner

Michael Brannock

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 01 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-8 and 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,2,4-8, 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application: Claims and Amendments

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/01/04 has been entered.

Applicant is notified that the amendments put forth on 10/01/04, have been entered in full.

Response to Amendment

Applicant is notified that the text of the statutes relied upon as the bases for the following claim rejections can be found in a prior Office action.

Applicant is notified that any outstanding objection or rejection that is not expressly maintained in this Office action has been withdrawn in view of Applicant's amendments, arguments and upon further consideration.

Applicant argues, essentially, that the Freitag sequences are only 20-50% homologous to rat and thus would not be expected to be at least 80% homologous to the human and therefore fall outside the bounds of what Applicant has asserted to not be individually distinct and independent. This argument is persuasive. Freitag provides the motivation to obtain the human molecules, however, the evidence from Ben-Arie et al. indicates that the artisan would not have a reasonable expectation of obtaining the claimed polynucleotides because of the tremendous

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number and variability of the clones obtained by Ben-Arie from the amplification of a single chromosome, see the Discussion.

Claim Rejections - 35 USC § 112

Claims 1, 2, 4-8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims contain the phrase “or a complement thereof” as in claim 1 or “, or a complement thereof, as in claim 5. There are several issues regarding these phrases in the context of the instant Applicant in. First, the phrase in claim 1 keeps changing after each of Applicant’s responses, from “, or the complement”, then “, or a complement thereof”, then “or the complement thereof”, to now “or a complement thereof”. The changing use of the comma is confusing and makes it unclear to which part of the sentence the phrase is meant to refer to. Second the use of the word “a” versus the word “the” in the phrase appears to change the bounds of the claim, i.e. the use of the phrase “the complement thereof” implies only one molecule of exactly the length of the reference molecule, whereas “a complement thereof” implies that not only the length could be different but perhaps mismatches could be incorporated as well. For the purposes of this examination these phrases will be treated as explained above.

Claims 1, 2, 4-8 and 11 stand rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility, as set forth in the prior Office action.

Applicant's arguments have been thoroughly addressed in the prior Office actions. Applicant argues arguments regarding the alleged membership in the family of OXR proteins have been fully considered but not deemed persuasive. There is no single substantial utility that is commonly shared among the members of the family of OXR proteins. Any substantial utility that any one member might have would arise from specific information regarding that member, e.g. that aberrant expression correlated with a specific disease state, or that the protein bound a specific ligand. No such specific information is disclosed in the instant specification regarding the protein encoded by SEQ ID NO: 224.

Claims 1, 2, 4-8 and 11 are also rejected under 35 U.S.C. § 112 first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation, as set forth previously.

Applicants' arguments regarding the 35 U.S.C. § 112 rejection as the corollary of the 35 U.S.C. § 101 rejection have been addressed above. Further more, the potential scope of enablement rejection, argued by Applicant, would apply to claims 1, 2, 4-8 and 11 which encompass variants of SEQ ID NO: 224 based on the broadest reasonable interpretation of the meaning to the phrase "a complement thereof", as discussed above.

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Claims 1, 2, 4, 5 are rejected under 35 U.S.C. 102(b) as being anticipated by The SIGMA PRODUCT CATALOGUE, 1993, page 743

As discussed above the claims require "a complement thereof". The specification at page 119 indicates that the sequence GGG is present at approximately position 327. SIGMA provide oligodeoxycytidylic acid, product number O 8628 which would be the complement of this sequence, see page 743.

Conclusion

Please note the new central fax number for official correspondence below:

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Brannock, Ph.D., whose telephone number is (571) 272-0869. The examiner can normally be reached on Mondays through Fridays from 10:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, Ph.D., can be reached at (571) 272-0961. Official papers filed by fax should be directed to 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MB



ELIZABETH KEMMERER
PRIMARY EXAMINER

December 12, 2004